IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 2:12-cv-03555(CFK)

DEFENDANT MERCK'S REPLY IN SUPPORT OF ITS MOTION FOR RECONSIDERATION OF THE COURT'S JULY 27, 2023 ORDER OR, ALTERNATIVELY, FOR CERTIFICATION OF INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. § 1292(b)

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(CONTINUED)

Page(s)

STATUTES

TABLE OF AUTHORITIES
(CONTINUED)

Page(s)

OTHER AUTHORITIES

INTRODUCTION

Plaintiffs' efforts to refute that reconsideration or certification for interlocutory appeal is appropriate here are unavailing. Plaintiffs seek to dodge controlling law, sidestep the conflict that now exists between this case and other cases ruling the opposite way on the same issues, and—most importantly—cannot explain away the divergence from this Court's decision in the FCA case. The simple fact is that no court has applied *Noerr-Pennington*'s sham exception to successful petitions submitted as part of non-adjudicative proceedings. And where FDA has *all* the relevant evidence in front of it for years yet continues to indicate no concerns regarding the relevant parts of the label for Merck's mumps vaccine, a non-expert jury should not be invited to second-guess FDA and conclude the opposite. Reconsideration or, at the least, certification for interlocutory appeal under 28 U.S.C. § 1292(b), is warranted. Relators recently noticed their appeal in the FCA case, so if this Court does not grant reconsideration, it should certify the Antitrust Decision for immediate appeal to allow the Court of Appeals to approach these cases as this Court has: jointly.

The Opposition is wrong from the start. It misstates both the standard of review governing reconsideration of interlocutory orders like this one and the summary judgment standard. It ignores Merck's explanation that the sham exception is limited to the adjudicative context. It fails to appreciate the import of this Court's FCA Decision, instead attacking this Court's reasoned conclusion that FDA's continued inaction in the face of its statutory duty to act indicates that any allegedly false or misleading statements were immaterial to the government's decision-making. From there, Plaintiffs invent entirely unsupported legal rules, and offer artificial distinctions and misinterpretations of the case law Merck cited. Plaintiffs go so far as to forsake their entire theory of the case and suggest that causation with respect to FDA decision-making is actually irrelevant. This change, made by Plaintiffs so that they could square this case with the FCA Decision, reinforces that reconsideration or certification is warranted.

ARGUMENT

I. Plaintiffs Misstate the Governing Legal Standing for Reconsideration of the Antitrust Decision.

Plaintiffs base their entire Opposition on an incorrect legal standard that ignores binding Third Circuit precedent. They say that reconsideration is permitted only if there has been "an intervening change in the law," "new evidence," or "to prevent clear error or manifest a injustice." Pls.' Opposition at 2, ECF No. 366 (the "Opp.") (quoting *Schneyder v. Smith*, 709 F. Supp. 2d 368, 383 (E.D. Pa. 2010)); *see also* Opp. at 3-4. That is the standard that applies to reconsideration of a final judgment, not an interlocutory order like the Antitrust Decision.

When it comes to interlocutory orders, a court has "inherent power" to reconsider and can do so "when it is consonant with justice [to] do so." *In re Energy Future Holdings Corp*., 904 F.3d 298, 310 (3d Cir. 2018) (citation omitted). At bottom, the relevant standard is whether the ruling at issue "might lead to an unjust result." *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009). This standard is much broader than reconsideration after final judgment. *See, e.g.*, *Gay v. A.O. Smith Corp.*, No. 19-cv-1311, 2022 WL 2829887, at *1 (W.D. Pa. Apr. 21, 2022) ("District courts generally possess more discretion to reconsider interlocutory orders than to reconsider final judgments."). Reconsideration here thus does not turn on whether there has been a change in law, new evidence, or a clear error. Instead, this Court can grant Merck's motion based only on the Court's assessment that Merck is correct.

II. This Court Should Reconsider the Sham Exception Holding.

Plaintiffs do not point to any decision concluding that a successful petition submitted as part of a non-adjudicative proceeding can be so objectively baseless as to trigger *Noerr-Pennington*'s sham exception. Their arguments as to why this Court should leave a novel holding in place both overlook governing case law and create a split with the FCA Decision. This Court

should reconsider its *Noerr-Pennington* holding and, on reconsideration, hold that the sham exception does not apply to Merck's responses to the FDA Form 483 and Warning Letter, and its biological product deviation reports ("BPDRs"). *See* Pls. Sealed Opp. at 8 n.14, ECF No. 367 (confirming those are Merck's communications with FDA that Plaintiffs assert were a "sham").

A. Plaintiffs Cite No Case Applying the Sham Exception in the Context of a Non-adjudicatory Setting.

Plaintiffs never address head-on Merck's explanation that courts have limited application of the sham exception to adjudicatory proceedings. *See* Opp. at 11-12. Only *adjudicatory* proceedings have the sort of clearly defined standards and rules against which a factfinder can measure the purported baselessness of a petition. *See* Opening Br. at 11-12, ECF 363-1 (citing *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 273 (3d Cir. 2017); *Mercatus Grp. LLC v. Lake Forest Hosp.*, 641 F.3d 834 (7th Cir. 2011); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1061 (9th Cir. 1998)). As Plaintiffs do not dispute, no court (other than in the Antitrust Decision) has found the sham exception could apply to *non-adjudicatory* agency communications.

Plaintiffs instead argue that the sham exception can apply when the petitioning activity involves an agency; FDA is an agency; and so the sham exception applies to Merck's communications with FDA. Opp. at 12. This simplification of the sham exception misses the point: The issue is not to *whom* petitioning activity was directed, but *the context* of the petitioning activity. If Plaintiffs were correct, then *Kottle* would have come out differently because Washington State's Department of Health is an agency. *See* 146 F.3d at 1059. But as the Ninth Circuit recognized, the context of the communications is what matters. *See, e.g.*, *id.* at 1062 ("The . . . determination by the Department bears many indicia of a true adjudicatory proceeding."). The Ninth Circuit thus proceeded to consider whether the sham exception applied to that adjudicative proceeding, ultimately concluding that the exception did not apply. *Id.* at 1063-64. Plaintiffs offer

no rationale for why this Court should break from this case law and extend the sham exception to the *non-adjudicative* context, because there is none.[1]

B. Even if the Sham Exception Applied, the FCA Decision Shows That Merck's Alleged Misrepresentations to the FDA Were Not "Objectively Baseless."

i. Plaintiffs Misunderstand the Summary Judgment Standard.

First, contrary to Plaintiffs' contention (Opp. at 4-7), this Court can and should rule on the objectively baseless prong at summary judgment because any purported dispute over the predicate facts in the underlying petitions will not affect the outcome of this case. *See* Opening Br. at 6. Regardless of whether Merck's submissions to FDA did or did not contain misrepresentations or omissions around "the potency and seroconversion rates on its label," Opp. at 6, this Court has already concluded in the FCA case that all available evidence strongly suggests that FDA has determined that the label is non-misleading in all material respects. *See* FCA Opinion at 30 ("Because these agencies are under a duty to review the information before them, the lack of response by both the FDA and CDC strongly indicate that Relators' allegations are not material. *Advanced Disposal Servs. E., Inc. v. N.L.R.B.*, 820 F.3d 592, 604 (3d Cir. 2016) (noting it is plaintiff's burden 'to show that the [agency] did not review the record' in administrative proceedings); 21 U.S.C. § 355(o)(4)(A) (requiring the FDA to promptly notify the responsible person if it 'becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the [FDA] determines should be included in the labeling of the drug'); *see also Petratos* [*v.*

[1] Plaintiffs' attempts at distinguishing *Mercatus Group* (Opp. at 12) are telling. They portray *Mercatus Group* as involving a "fraudulent misrepresentation" exception that the Third Circuit has rejected, but, as explained *infra* at 14-15, that is wrong. And the fact that *Mercatus Group* did not concern petitioning activity involving an agency is neither here nor there; what matters is that *Mercatus Group* held that the sham petition is limited *adjudicatory proceedings*. *See* 641 F.3d at 844. Moreover, Plaintiffs' reliance on *Flonase* (at 12) is unavailing; as already explained, that case concerned a citizen petition, which has clearly defined rules and procedures, *see* Opening Br. at 11. *Flonase* thus favors Merck, not Plaintiffs.

Genentech, Inc.], 855 F.3d [481,] 490 [(3d Cir. 2017)] (affirming dismissal of FCA suit on materiality grounds)."). This Court's conclusion in the FCA Decision, as quoted above and based on the same record here, can only mean that any alleged misrepresentations or omissions were immaterial to FDA's decision-making about how to respond after the Form 483, Warning Letter, and BPDRs were submitted. Merck was and remains successful to this day in its explanations of the circumstances to the FDA, and its submissions were thus not shams as a matter of law. *See* Opening Br. at 15; *see also infra* at 5-11. Thus, in this context, predicate facts about the underlying petitioning activity have no bearing on "the outcome of the suit" and cannot defeat summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

Plaintiffs insist otherwise because their theory of harm depends on those facts. *See* Opp. 6. But the materiality question is *not* whether the predicate facts matter to Plaintiffs' theory; it is whether those facts "might affect the outcome of the suit." *Anderson*, 477 U.S. at 248. And Plaintiffs offer nothing to explain why or how any dispute over the predicate facts in Merck's submissions can overcome the legal conclusion—driven by governing law and this Court's FCA Decision—that the sham exception is inapplicable even giving Plaintiffs the benefit of their contention that those petitions contained misrepresentations or omissions.

ii. Plaintiffs Fail to Explain How FDA's Inaction Can Mean That Merck's Submissions Were Immaterial in the FCA Case but Not in This Case.

As this Court recognized, Plaintiffs' theory is that Merck submitted false and misleading information to FDA to support its mumps vaccine label to prevent GSK from being able to mirror that label and enter the market. *See* Antitrust Decision at 14; Pls.' Summ. J. Opp. at 15-30, ECF No. 279. In the FCA case, Relators likewise contend that Merck's submissions led to the same false or misleading statements on Merck's label. *See* FCA Decision at 23-24. And in that case, this Court found that any alleged falsity in the label is immaterial because, among other reasons,

FDA has received all the facts and has not required Merck to revise the statements that Relators, like Plaintiffs, challenged. *See id.* at 30 (citing, *inter alia*, 21 U.S.C. § 355(o)(4)(A)). That holding means that, as a matter of law, those same alleged misrepresentations or omissions by Merck are immaterial under the sham exception to *Noerr-Pennington*. *See* Opening Br. at 13-14.

Plaintiffs' responses are unpersuasive. Latching onto the Third Circuit's direction that a misrepresentation is material if it "affects the very core of a litigant's . . . case," *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 124 (3d Cir. 1999), Plaintiffs contend that the FCA materiality standard is different than the sham-exception materiality standard. *See* Opp. at 7-8; *see also id.* at 13-14. But Plaintiffs tellingly omit the *actual* materiality standard that applies in the sham-exception context, that is, the standard for determining *when* a misrepresentation goes to a petition's core: when "the government's action was . . . dependent upon the misrepresented information." *Cheminor Drugs*, 168 F.3d at 124. That standard is functionally identical to the FCA standard, which likewise considers the government's response to the allegedly misrepresented information. *See Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 193 (2016). If a reasonable person would "attach importance" to the alleged misrepresentation, the alleged misrepresentation is material under the FCA. *Id.* (internal quotation marks omitted). The words might be different but the function is the same: Both FCA materiality and sham-exception materiality consider the government's reaction to the allegedly misrepresented information. This Court's holding in the FCA Decision that the alleged misrepresentations were not "persuasive" enough for FDA to change its labelling decisions, FCA Decision at 33, thus necessarily means that FDA's actions in response to Merck's submissions were "not dependent upon the misrepresented information," *Cheminor Drugs*, 168 F.3d at 124.

Plaintiffs next argue that the FCA Decision's materiality holding is irrelevant in this case because the FCA case concerned the CDC's continued purchase of Merck's mumps vaccines, whereas this case concerns "Merck's submissions to the *FDA*." Opp. at 8. That too is wrong. FDA's continued inaction in the face of the evidence was a crucial aspect of this Court's immateriality holding in the FCA case. As this Court explained, "*the FDA* has not taken any action in response to this lawsuit or Dr. Kessler's submissions. Because these agencies are under a duty to review the information before them, the lack of response by both *the FDA* and CDC strongly indicate that Relators' allegations are not material." FCA Decision at 30 (emphases added) (citing *Advanced Disposal Servs. E.*, 820 F.3d at 604; 21 U.S.C. § 355(o)(4)(A)). "The reality," this Court continued, "is that the Government does have knowledge of all of the facts, but these facts were simply not persuasive to the CDC, *or any other agencies*, to prompt them to take any action." *Id.* at 33 (emphasis added). One last time: "The CDC, *the FDA*, and the DOJ have been given all the evidence. And with knowledge of this evidence, . . . the FDA has continued to license Merck's mumps vaccines." *Id.* at 37 (emphasis added). FDA's continued inaction was, in short, a keystone to this Court's immateriality holding in the FCA case. It had to be, given that FDA is the agency with the statutory duty to maintain the accuracy of product labels under 21 U.S.C. § 355(o)—a statute that Plaintiffs completely ignore even after this Court expressed its reliance upon it.

Plaintiffs fall back on asserting that "whether a petition is a sham is generally a question of fact for the jury." Opp. at 9 (ultimately citing *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011)). Yes, but summary judgment is granted in favor of the movant when there is insufficient evidence "favoring the nonmoving party for a jury to return a verdict for that party." *Anderson*, 477 U.S. at 249. For that reason, courts routinely rule on the sham exception at summary judgment. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868

F.3d 132, 143 (3d Cir. 2017) (holding on summary judgment that plaintiffs "failed to establish a genuine dispute of fact . . . to whether [the defendant] engaged in sham litigation"); *Cheminor Drugs*, 168 F.3d at 120 (same); *Campbell v. Pennsylvania Sch. Bds. Ass'n*, 972 F.3d 213, 227 (3d Cir. 2020) (same). In light of the FCA Decision, this Court can and should do the same.

Finally, Plaintiffs all but disclaim their theory of the case when they argue that "the labels are irrelevant to this Court's sham analysis," which is instead limited to "Merck's submissions to the FDA." Opp. at 13. Until now, Plaintiffs' theory has been that Merck's submissions affected the information on the labels, which in turn made it harder for GSK to enter the market. As this Court put it, "Plaintiffs contend that Merck's submissions to the FDA and, in turn, its labels for its mumps vaccines contain false and misleading information . . . and *because of this conduct*, Merck precluded GSK from obtaining a license." Antitrust Decision at 5 (emphasis added).[2] It is therefore entirely appropriate to consider that, when FDA was presented with evidence of the supposed misrepresentations in Merck's petitions, it did not require Merck to change the label.[3]

iii. Plaintiffs Fail to Grapple With Merck's Success.

The sham exception analysis "*requires* consideration, *inter alia*, of the outcome of the proceedings." *Cheminor Drugs*, 168 F.3d at 124 (emphasis added). And as the Ninth Circuit has

---

[2] *See also, e.g.*, Pls.' Summ. J. Opp. at 15-21 (discussing several of Merck's submissions to the FDA that, in Plaintiffs' words, "had the desired result" of keeping "the 24-Month Shelf Life on the Mumps Vaccine label and stav[ing] off competition"); *id.* at 23-28 (contending that the submission of Protocol 007 data to the FDA was "a key component of Merck's market preservation strategy"); *id.* at 28-30 (arguing that Merck submitted supplemental Biologics License Applications with false and misleading information "to preserve the 24-Month Shelf Life and Seroconversion Claim on its Mumps Vaccine labels and keep GSK out of the market").

[3] Plaintiffs are also wrong that this case is not over if this Court holds on reconsideration that the sham exception does not apply. *See infra* at 18-19. Although Merck's labels might not be subject to *Noerr-Pennington*, the FCA decision indicates that those labels are not false or misleading. Plaintiffs therefore cannot—and in fact have not—pointed to any public statement that would be misleading.

recognized, the sham exception cannot apply when the defendant "prevailed." *Kottle*, 146 F.3d at 1063. This accords with common sense: A petition cannot be "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" if the party *achieved* "success on the merits." *Professional Real Estate Invs. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). And, as Merck has explained, the outcome of the relevant proceedings resulted in success for Merck—a success the FCA Decision confirms by recognizing that FDA continues to stand by its decision. *See* Opening Br. at 14-15.

Plaintiffs fault Merck for failing to cite a case "that applies *lack* of regulatory action to dismiss an antitrust case in a similar context." Opp. at 9. First, it makes sense that there is no such case because the exception does not apply in the non-adjudicatory setting. In any event, Merck cited and discussed a case that's far closer to home: this Court's FCA Decision. That case is predicated on *the exact same theory* as this case and includes the *exact same submissions* as this case. And, crucially, this Court granted Merck summary judgment based in significant part on the *lack of regulatory action*. This lack of regulatory action is a marker of success if there ever was one. *See* Opening Br. at 14-15. As this Court recognized in the FCA case, a lack of regulatory action has unique legal significance in a case where the relevant agency (FDA) faces an affirmative statutory duty *to act* if it is presented with evidence that shows that a drug label is misleading.

All but admitting that the FCA Decision indicates a successful outcome for Merck, Plaintiffs suggest in a footnote that the FCA Decision is wrong because the FDA Commissioner and other FDA officials with whom Dr. Kessler shared his analysis of flaws concerning this mandatory childhood vaccine may have simply not read his submissions. *See* Opp. at 11 n.21. But, as this Court explained in the FCA Decision, FDA is "under a duty to review the information before [it]." FCA Decision at 30 (citing *Advanced Disposal Servs. E.*, 820 F.3d at 604; 21 U.S.C.

§ 355(o)(4)(A)). And "the lack of response by . . . FDA . . . strongly indicate[s] that Relators' allegations are not material." *Id.* This Court has thus already rejected as inconsistent with the duty of regularity Plaintiffs' suggestion that FDA was just too busy to consider the views of a former FDA Commissioner about the safety and labeling of a vaccine given to many millions of children a year. Plaintiffs' very belated and strained suggestion is also at odds with the fact that FDA demonstrated its ability to multitask throughout the pandemic: During this time, FDA continued to act on drug label submissions, new drug applications, and every other type of regulatory submission it receives pursuant to its statutory responsibilities.

Plaintiffs also advance the novel argument that this Court can ignore Merck's success because the proceedings were private and because Merck's alleged misrepresentations were omissions rather than affirmative misstatements. *See* Opp. at 9-10. These assertions seem directed at this Court's holding that the submissions were *Noerr-Pennington* protected petitioning activity. But in any event, Plaintiffs offer no case in support of their proposed rule that the sham exception can apply only to public advocacy. Plaintiffs are similarly mum about case law supporting their theory that omissions in the sham context are unlike other omissions, which can constitute fraudulent misrepresentations. *See, e.g.*, *Elbeco Inc. v. Nat'l Ret. Fund*, 128 F. Supp. 3d 849, 859-860 (E.D. Pa. 2015). Plaintiffs' silence speaks volumes. In any event, *even if* the sham exception could apply differently in a situation where "truthful information was concealed from the government," Opp. at 10, FDA now has all the information. And it has not required Merck to change is labels. *See supra* at 7. So even by Plaintiffs' own logic, there is no reason to water

down the sham exception and permit a non-expert jury to second-guess the objective reasonableness of Merck's submissions.[4]

III. This Court Should Reconsider the Antitrust Injury Holding.

Plaintiffs' Opposition confirms that reconsideration is warranted. Plaintiffs do not dispute that FDA has all the information of Merck's allegedly anticompetitive conduct. And Plaintiffs do not dispute that FDA has taken no action in light of that information—that is, that FDA has not required Merck to correct the statements Plaintiffs insist are false or misleading. Plaintiffs simply ask this Court to overlook the consequences of that inaction, which indicates that FDA *would not have* required Merck to change its labels in a way that would make them easier for GSK to mirror absent Merck's allegedly anticompetitive conduct.[5] Plaintiffs' theory of antitrust injury thus fails as a matter of law. *See Wellbutrin*, 868 F.3d at 167.

Plaintiffs throw a few arguments at the wall. None stick. They again run from their own theory of the case, contending that "[t]he key question here is *not* what the FDA would have done had Merck disclosed what it knew about its vaccine; the question is what *GSK* would have done if Merck had disclosed the truth." Opp. at 14. Plaintiffs' new theory (such as it is) that FDA's

---

[4] Plaintiffs close with the confusing point that "FDA action is no longer essential to remedy the antitrust violation alleged in this case." Opp. at 11. It is difficult to know what Plaintiffs mean. Plaintiffs seek damages for the period when GSK was unable to mirror Merck's FDA-approved label because, according to Plaintiffs, Merck submitted false or misleading information to FDA. The question here is whether those submissions are immune from antitrust liability under *Noerr-Pennington*. Regardless of what Plaintiffs mean, the fact remains that FDA continues to have a statutory responsibility to change Merck's label if something is wrong with it, whether it implicates antitrust liability or not.

[5] To recap, Plaintiffs' theory of antitrust injury is that absent Merck's alleged anticompetitive conduct, (1) FDA would "likely" have lowered the bar for regulatory approval by making Merck's label less difficult to "mirror" and (2) GSK would have entered the market earlier. *See* Pls.' Summ. J. Opp. at 40-44; *accord* Antitrust Decision at 31 ("Plaintiffs allege that they have created a triable issue of fact as to whether Merck's conduct materially caused their harm because they have put forth evidence that . . . Merck kept GSK off the market by maintaining false and misleading statements on the mumps vaccine labels.").

inaction is irrelevant to their antitrust injury causal chain is brand new; until now, FDA's approval of Merck's labels has been the crucial causal link. *See supra* at 8 & n.2. Inconsistency aside, Plaintiffs' new theory makes no sense. In a case about the statements on an FDA-approved label for which a competitor would have had to show non-inferiority, FDA's actions related to the label's statements cannot be irrelevant.[6]

In any event, as quickly as Plaintiffs adopt a new no-FDA theory, they drop it, insisting that FDA's approval of Merck's labels did not break the causal chain because that approval was a "foreseeable consequence of" Merck's allegedly anticompetitive conduct. Opp. at 15. Plaintiffs continue to miss the point. As this Third Circuit explained in *Wellbutrin*, to survive summary judgment, Plaintiffs must "produce evidence from which a reasonable jury could conclude that it is more likely than not that [the competitor] would have obtained" regulatory approval absent the challenged conduct. 868 F.3d at 167. Plaintiffs cannot show that *GSK* would have obtained regulatory approval sooner absent Merck's claims because FDA's continued inaction in the face of all the evidence reveals that FDA does not view Merck's label as containing any false statements. *See* Opening Br. at 18. That is, *regardless* of whether Merck engaged in the alleged anticompetitive conduct, the FCA Decision indicates that FDA *would not have required Merck to change its labels*. That fact alone severs the causal chain.[7]

---

[6] Plaintiffs' bizarre suggestion that FDA no longer needed to correct false and misleading statements on Merck's label after "GSK was ultimately able to access Merck's PPD ELISA," Opp. at 15, is inconsistent with governing law, which requires FDA to take action in response to misleading labels regardless of whether there is one or more competitors on the market. *See* 21 U.S.C. § 355(o).

[7] Plaintiffs do not even attempt to respond to the fact that, after the FCA Decision, the Food, Drug, and Cosmetic Act's "private action bar" precludes Plaintiffs' suit. *See* Opening Br. at 17 n.7.

Plaintiffs do not argue that *Wellbutrin* is wrong, or that Merck misunderstands its holding. Plaintiffs instead assert that *Wellbutrin* does not apply because that case concerned a "blocking patent" and this case concerns FDA's labelling requirements. *See* Opp. at 15 n.29. That is a distinction without a difference. *Wellbutrin* explains when "a regulatory . . . bar can break the chain of causation in an antitrust case." 868 F.3d at 165. There is nothing in that case indicating that the relevant "regulatory bar" must be a patent. Quite the opposite: In support of its causation rule, *Wellbutrin* relied on many other cases outside of the patent context, including an Eighth Circuit case where the "regulatory . . . bar" was the labelling requirements of the Food, Drug, and Cosmetic Act, *see id.* at 165 (discussing *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-791 (8th Cir. 2006))—the same regulatory scheme blocking GSK's entry in the market. *Wellbutrin* is thus on all fours with this case.

Retreating, Plaintiffs lean on certain record material cited in the Antitrust Decision, *see* Opp. at 14-15, and insist that proximate question is a question of fact for the jury, *see id.* at 15. But Merck explained why that material does not bear on FDA's decision-making, *see* Opening Br. at 17, and Plaintiffs do not show otherwise. This material thus cannot overcome Plaintiffs' failure *as a matter of law* to show that, in the but-for world, FDA "would have" changed its actions with respect to any statements on Merck's label.

IV. Alternatively, This Court Should Certify Its Order for Interlocutory Appeal.

This Court's *Noerr-Pennington* and antitrust-injury holdings satisfy every requirement for interlocutory appeal under 28 U.S.C. § 1292(b). *See* Opening Br. at 20-25. The Relators recently noticed their appeal of the FCA Decision, *see* Notice of Appeal, ECF No. 353, *Krahling v. Merck*, No. 10-cv-04374-CFK (Aug. 24, 2023), and it makes logical sense that these cases would continue to travel together as they have since their inception. Put simply, principles of judicial economy

and efficiency militate in favor of certifying this Court's Antitrust Decision for interlocutory appeal. Plaintiffs' arguments to the contrary are, at best, half-hearted.

A. Plaintiffs Do Not Contest That Both the *Noerr-Pennington* and Antitrust Injury Holdings Concern a Controlling Question of Law.

Section 1292(b)'s first requirement is that the relevant issue be "a controlling question of law." 28 U.S.C. § 1292(b). Plaintiffs do not dispute that both the *Noerr-Pennington* and antitrust injury holdings involve such controlling questions. That requirement is therefore met.

B. Plaintiffs Cannot Distinguish Away Conflicting Cases.

Section 1292(b)'s second requirement is that there must be a "substantial ground for difference of opinion" as to the issue, 28 U.S.C. § 1292(b), such as a "conflicting and contradictory opinion[]" on the same issue, *Pereira v. Foot Locker, Inc.*, No. 07-cv-2157, 2010 WL 300027, at *4 (E.D. Pa. Jan. 25, 2010) (quoting *Oyster v. Johns-Manville Corp.*, 568 F. Supp. 83, 86 (E.D. Pa. 1983)). This Court's conclusion that *Noerr-Pennington* applies to the non-adjudicative context contradicts *Mercatus Group*. *See* Opening Br. at 22-23. Its conclusion that successful petitioning can nonetheless be a sham contradicts with *Cheminor Drugs* and *Kottle*. And its antitrust injury holding conflicts with *Wellburtin* and *In re Mallinckrodt*.

Plaintiffs' attempts at distinguishing these opinions fail. Plaintiffs are wrong to say that "*Mercatus* is based on a separate exception for fraudulent misrepresentation not available in the Third Circuit." Opp. at 18. In *Cheminor Drugs*, the Third Circuit held that fraudulent misrepresentations "will preclude *Noerr-Pennington* immunity" where those misrepresentations are "material" in the sense that "the government's action was . . . dependent upon the mispresented information." 168 F.3d at 124. Citing *Cheminor Drugs*—twice—the Seventh Circuit in *Mercatus Group* adopted that same rule: "[A] misrepresentation renders an adjudicative proceeding a sham only if the misrepresentation (1) was intentionally made, with knowledge of its falsity; and (2) was

material, in the sense that it actually altered the outcome of the proceedings." 641 F.3d at 843. The Third and Seventh Circuits agree on the point that material misrepresentations preclude *Noerr-Pennington* immunity. This Court's holding that the sham exception can apply to petitions submitted in the *non-adjudicative* context squarely conflicts with the Seventh Circuit's holding that the sham "exception does not apply at all outside of adjudicative proceedings." *Id.* at 844.

Plaintiffs' confusion appears to stem from the fact that the Seventh Circuit has separated "the sham exception" into two strands: "(1) sham lawsuits[,] and (2) fraudulent misrepresentations," *id.* at 842; whereas the Third Circuit bundles the two under the general "objectively baseless" inquiry, *see Cheminor Drugs*, 168 F.3d at 123-124. This is not a difference in substance. As the Third Circuit explained in *Cheminor Drugs*, its "approach in requiring that misrepresentations must be *material* to bar *Noerr-Pennington* immunity is consistent" with the D.C. and the Ninth Circuits, *see id.* at 124 n.12—the two circuits that had already adopted similar categories the Seventh Circuit later adopted in *Mercatus Group*. Like in the Third Circuit, the Seventh Circuit's "fraud" inquiry is one way of determining whether the petition was "objectively baseless." *See Mercatus Grp.*, 641 F.3d at 842-843. And *Mercatus Group*'s double citation to *Cheminor Drugs* should resolve Plaintiffs' concerns that the cases involve different exceptions.

Plaintiffs next contend that there is no conflicting authority on the issue whether successful petitioning activity can be so objectively baseless as to constitute a sham. *See* Opp. at 18-19. According to Plaintiffs, the Ninth Circuit case *Kottle* is inapposite because the petitioning activity in that case arose in the context of an adjudicative proceeding with ample safeguards. *Id.* at 18. But Plaintiffs do not explain why those safeguards have any bearing on the Ninth Circuit's holding that the defendant's "victory before the Department necessarily indicates that [the defendant's] position was not objectively baseless." *Kottle*, 146 F.3d at 1063.

Indeed, Plaintiffs' attempts at distinguishing *Kottle* serve to heighten the substantial ground for difference of opinion: All of their supposed distinctions are factors the Ninth Circuit considered when determining that the *Kottle* petitioning activity occurred in the context of "a true adjudicatory proceeding" and was thus subject to the sham exception. *Id.* at 1062. Had this Court applied those same factors, it would have held that sham exception does not apply to Merck's petitioning activity. After all, the administrative process at issue here did not include "public hearings, . . . written and oral arguments, . . . representation by counsel," or the ability "to question witnesses." *Id.* Under *Kottle*, then, Merck's submissions were not part of "a true adjudicatory proceeding" and the sham exception is inapplicable. *Id.*

Plaintiffs argue that this Court did not break with *Cheminor Drugs* when it failed to consider Merck's success because that case listed success as one of several factors courts are "requir[ed]" to consider. Opp. at 18-19. But that is the point: *Cheminor Drugs* holds that courts *must* consider the outcome of the proceedings, which the Antitrust Decision does not do. Moreover, *Cheminor Drugs* did not concern successful petitioning activity. *See* 168 F.3d at 120 (explaining that defendant withdrew complaint before final determinations were made). That case nevertheless emphasized that the outcome of the proceedings was a crucial factor in the objectively baseless inquiry, indicating that there is a substantial ground for difference of opinion as to whether that factor is *preclusive* in the context of a successful petition.

Finally, Plaintiffs argue that there is no ground for difference of opinion as to this Court's antitrust injury holding because *Wellbutrin* and *In re Mallinckrodt PLC*, 638 B.R. 57 (D. Del. 2021), are distinguishable. Opp. at 19. But, as explained, that *Wellbutrin* concerned a blocking patent is irrelevant to its holding. *See supra* p. 13. And Plaintiffs' insistence that *Mallinckrodt* is inapposite because it arose in the bankruptcy context and concerned "factual findings after [a

bench] trial" is misplaced. Opp. at 19. Applying *Wellbutrin* and other Third Circuit case law, *Mallinckrodt* held that the relevant legal standard for antitrust injury in a case where a competitor's entry into the market depends on securing a regulatory license is whether, "but for" the alleged anticompetitive conduct, "the regulatory authority *would have* granted a competitor approval." 638 B.R. at 72 (emphasis added). *Mallinckrodt* confirms the substantial ground for difference of opinion on the *legal standard*, supporting interlocutory review.

C. Plaintiffs' Concerns About Delay Do Not Outweigh the Reasons Favoring Certification.

Finally, certifying this Court's order will "materially advance the ultimate termination of the litigation." *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754 (3d Cir. 1974) (citation omitted). Conclusively resolving either the *Noerr-Pennington* issue or the antitrust injury issue will end this case. At the least, resolving the *Noerr-Pennington* issue will conclusively resolve a complex issue that threatens to complicate an already complicated antitrust case. *See* Opening Br. at 25.

Plaintiffs' responses miss the mark. First, Plaintiffs fail to recognize that this factor "is 'closely tied to the requirement that the order involve a controlling question of law.' " *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 600 (E.D. Pa. 2008) (quoting 16 Charles A. Wright et al., FEDERAL PRACTICE AND PROCEDURE § 3930, 423 (2d ed. 1996)). Plaintiffs' implicit concession that these issues are controlling questions of law thus severely undermines their concerns about delay.

As to those concerns, the upshot of Plaintiffs' argument is that this case has already taken long enough. *See* Opp. at 20-21. Plaintiffs cite a few cases for this proposition, but none look anything like this case. *Hulmes v. Honda Motor Co.*, 936 F. Supp. 195, 211 (D.N.J. 1996), and *Averhart v. Commc'nWorkers of America*, No. 10-cv-6163, 2016 WL 1162628, at *2 (D.N.J. Mar. 24, 2016), concerned cases where trial was scheduled for the imminent future; this case does not.

Indeed, as Plaintiffs point out, class certification—not trial—is the next step. *See* Opp. at 21. *Hulmes*, moreover, concerned an issue that would not obviate the need for trial, *see* 936 F. Supp. at 211; this case does. And the trial that would have been avoided by immediate appeal in *Burella v. City of Phila.*, No. 00-cv-0884, 2010 WL 235110, at *6 (E.D. Pa. Jan. 14, 2010), would not have been "expensive, lengthy and complicated"; this one is guaranteed to be all of those.

Plaintiffs' inability to find an analogous case confirms that, when considering whether an interlocutory appeal will materially advance this case's ultimate termination, this Court should focus on the future, not the past. *See* Opening Br. at 24-25. And as to that future, Plaintiffs do not refute that, should the Third Circuit rule in favor of Merck on antitrust injury, this case will be over. *See id.* at 25. Plaintiffs instead focus on the *Noerr-Pennington* issue, contending that, "even if this Court somehow erred in its sham analysis," Plaintiffs can proceed based on Merck's public statements. Opp. at 21. This argument does not address Merck's point that resolving the sham exception on appeal will resolve a complex issue, an independent reason for certification. *See Knipe*, 583 F. Supp. 2d at 600 (explaining that one relevant factor is "whether the trial would be simplified by the elimination of complex issues"). Nor does it grapple with the fact that, should the Third Circuit reverse on the *Noerr-Pennington* issue, this Court's finding that FDA has tacitly affirmed the accuracy of the label precludes any of Merck's relevant public statements from being inaccurate, let alone inaccurate in a way that frustrated competition. *See* Opening Br. at 24 & n.9. The case would thus effectively be over.

CONCLUSION

For these reasons and those in Merck's memorandum of law in support of its motion, this Court should grant reconsideration and enter summary judgment in favor of Merck. Alternatively, this Court should issue an order certifying the Antitrust Decision for interlocutory appeal or amend the Antitrust Decision to so state.

August 31, 2023

Respectfully submitted,

/s/ Lisa C. Dykstra

Lisa C. Dykstra
R. Brendan Fee
Zachary M. Johns
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: 215-963-5000
lisa.dykstra@morganlewis.com
brendan.fee@morganlewis.com
zachary.johns@morganlewis.com

Dino S. Sangiamo
Sally W. Bryan
Kathleen Hardway
VENABLE LLP
750 E. Pratt Street, Suite 900
Baltimore, MD 21202
Telephone: 410-244-7400
DSSangiamo@Venable.com
SRBryan@Venable.com

Counsel for Defendant
Merck Sharp & Dohme LLC
(f/k/a Merck & Co., Inc.)

CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2023, a true and correct copy of the foregoing was filed electronically and served on all counsel of record via operation of the CM/ECF System.

Dated: August 31, 2023

/s/ Lisa C. Dykstra
Lisa C. Dykstra

Counsel for Defendant
Merck Sharp & Dohme LLC
(f/k/a Merck & Co., Inc.)